## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Daniel Tod Smithey, et al. :

APPLICATION NO.: Filed Herewith : Examiner: To be Assigned

FILING DATE: Concurrent Herewith : Group Art Unit: To be Assigned

TITLE: Solid Compositions of Low-Solubility Drugs and :

Poloxamers

Hon. Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a).

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).

A prompt and favorable response is earnestly solicited.

Respectfully submitted.

Date: June 28, 2006 / Carmella A. O'Gorman /
Carmella A. O'Gorman
Attorney for Applicant(s)

Reg. No. 33,749

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340

(860) 686-1847

| INFORMATION DISCLOSURE CITATION |                 |                 |         |        |              |      |         | NO. PC3202   |              | RIAL NO.            | Filed H        | Filed Herewith |                    |     |
|---------------------------------|-----------------|-----------------|---------|--------|--------------|------|---------|--------------|--------------|---------------------|----------------|----------------|--------------------|-----|
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| YAMINED                         |                 |                 |         | DOCI   | IMENIT NI IN |      | S. PATE | VI DO        | CUMENTS      | NAME                | CLASS          | SUBCLASS       | FILING<br>IF APPRO | DAT |
| EXAMINER<br>INITIAL             |                 | DOCUMENT NUMBER |         |        |              |      |         |              | DATE         | NAME                | CLASS          | SUBCLASS       | IF APPRO           | PRI |
|                                 | US              | 6               | 2       | 4      | в            | 3    |         | •            | 6/19/2001    | Patel, M.V., et al. | 424            | 497            |                    | _   |
|                                 | US              | 6               | 3       |        | θ            |      |         | •            | 4/9/2002     | Chen, et al.        | 424            | 464            |                    |     |
|                                 | US              | 6               | 2       |        | 4            | •    | 8       | 1            | 7/24/2001    | Zhang, H., et al.   | 424            | 451            |                    |     |
|                                 | US              | 6               | 3       | 4      |              | 0    |         | ٠            | 11/13/2001   | Jain, R.A., et al.  | 424            | 497            |                    |     |
|                                 | US              | 6               | 3       |        |              | 3    | 0       | 0            | 5/28/2002    | Straub, J., et al.  | 424            | 486            |                    |     |
|                                 | US              | 2002            | 0       | 0      | 0            | •    |         | 51           | 1/17/2002    | Hageman, M., et al  | . 514          | 406            |                    |     |
|                                 | US              | 2002            | 0       | 0      | 1            | 2    | 7       | 04           | 1/31/2002    | Pace, G.W., et al.  | 424            | 486            |                    |     |
|                                 | US              | 2002            | 0       | 0      | 4            | 0    | 0       | 51           | 4/4/2002     | Lee, H.B., et al.   | 514            | 406            |                    |     |
|                                 | US              | 2001            | 0       | 0      | 3            |      | 9       | 59           | 11/01/2001   | Gabel, et al.       | 514            | 411            |                    |     |
|                                 |                 |                 |         |        |              |      |         |              |              |                     |                |                |                    | _   |
|                                 |                 |                 |         |        |              | FORE | IGN PA  | TENT         | DOCUMENT     | s                   | -              |                |                    | _   |
|                                 | DOCUMENT NUMBER |                 |         |        |              |      |         | DATE COUNTRY |              | CLASS               | CLASS SUBCLASS | TRANSL         | ATR                |     |
|                                 |                 |                 |         |        |              |      |         |              |              |                     |                |                | YES                | h   |
|                                 | EP              | 9               | 3       | 9      | 3            | 7    | 1       | 5            | 11/7/2001    | EPO                 | A61K           | 9/14           |                    |     |
|                                 | EP              | 1               | 1       | 9      | 3            | 2    | ,       | A            | 5/30/2001    | EPO                 | A61K           | 31/19          |                    |     |
|                                 | wo              | 9               | 7       | 9      | 2            | 7    | 1       | 7            | 1/23/1997    | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | 9               | 9       | 9      | 1            | ,    | 9       | 4            | 5/6/1999     | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | 0               | 2       |        | 1            | ,    | 9       | 4            | 2/14/2002    | International       | A61K           | 9/04           |                    |     |
|                                 | wo              | 0               | 2       |        | 3            | 1    | 9       | 4            | 2/21/2002    | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | 0               | 1       | 3      | 1            | 1    |         | A            | 5/17/2001    | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | 0               | 1       | 3      | 1            | 1    |         | 4            | 5/17/2001    | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | 0               | 1       |        | 1            | 1    | 9       | 5            | 7/5/2001     | International       | A61K           | 9/14           |                    |     |
|                                 | wo              | ٠               | 1       | ,      |              | ,    | ,       | 4            | 8/2/2001     | International       | A61K           | 9/14           |                    | -   |
|                                 | wo              | 0               | 1       | 7      | 4            | 3    | 5       | 7            | 10/11/2001   | International       | A61K           | 9/14           |                    | -   |
|                                 | wo              | 0               | 1       | 8      | 0            | 8    | 2       | 8            | 11/1/2001    | International       | A61K           | 9/00           |                    | -   |
|                                 | wo              | 0               | 1       | 9      | 7            | 8    | 5       | 3            | 12/27/2001   | International       | A61K           | 47/12          |                    | _   |

| INFORMATIO   | N DISCLOSURE CITATION   | ATTY. DOCK  | ET NO. PC32026A            | SERIAL NO. | Filed Herewith |  |  |  |  |  |
|--|---|-------------|----------------------------|------------|----------------|--|--|--|--|--|
| (Use seve  | eral sheets if necessary)   | APPLICANT   | Daniel Tod Smithey, et al. |            |                |  |  |  |  |  |
|  |   | FILING DATE | Concurrent Herewith        | GROUP      | To be assigned |  |  |  |  |  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |   |             |                            |            |                |  |  |  |  |  |
|  | X. Xu and P.I. Lee, "Programmable Drug Delivery from an Erodible Association Polymer System", Pharmaceutical Research, 10:8(1993), pp. 1144-1152. |             |                            |            |                |  |  |  |  |  |
|  |   |             |                            |            |                |  |  |  |  |  |
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| EXAMINER   |   | C           | DATE CONSIDERED            |            |                |  |  |  |  |  |
| EXAMINER Initial if reference considered, whether or not distrion is in conformance with MPEP 609, Dawline through citation if not in conformance and not considered. Include copy of this form with next communication to applicant |   |             |                            |            |                |  |  |  |  |  |

Conforms with FORM PTO-FB-A820

INFORMATION DISCLOSURE